REMARKS/ARGUMENTS

I. Status of the Claims

Claims 1-5, 7-15, 21-25 and 27-35 are pending.

Claims 13-15 and 33-35 are withdrawn from consideration by the Examiner as being directed to non-elected subject matter.

Claims 21-25 and 27-32 are allowed. Claims 2-5, 8, 9 and 12 are identified as allowable, but are rejected as depending from a rejected base claim.

In the "Office Action Summary," the Examiner indicated that claims 1-5, 7-15, 21-25 and 27-35 are subject to a restriction and/or election requirement. However, no such requirement is set out in the "Detailed Action" section of the Office Action. Accordingly, the indication that a restriction and/or election requirement is pending is believed to be in error. The Examiner is requested to confirm that no restriction and/or election requirement is pending, in the next Official Action.

No claims are amended, added or deleted.

By this Response, no new matter has been added to the application.

II. Response to Rejection Under 35 U.S.C. §102(b)

Claims 1, 7, 10 and 11 are rejected as allegedly being anticipated by Frazer et al., WO 98/23635 ("Frazer"). The Examiner asserts that Frazer anticipates the rejected claims because, according to the Examiner, Frazer teaches a chimeric peptide of 2-4 amino acids attached to a promiscuous T helper cell epitope from a variety of sources and, further, teaches use of the composition to generate an immune response. The rejection is respectfully traversed on the grounds that Frazer does not disclose a chimeric peptide comprising the first 2-5 amino acid residues from the free N- or free C-terminus of a naturally-occurring internal peptide cleavage product that is formed by proteolytic cleavage of a precursor protein or a mature protein. *See* claim 1.

The Examiner acknowledges that the claims recite that chimeric peptides include 2-5 amino acids from the free N- or free C-terminus of a naturally-occurring internal peptide cleavage product that is formed by proteolytic cleavage of a precursor protein or a mature protein. The

Examiner, however, takes the position that the recited limitation is "merely a product by process" and then fails to accord the limitation any weight. The Examiner's position is not well taken. The limitation that the claimed chimeric peptides include 2-5 amino acids from the free N- or free C-terminus of a naturally-occurring internal peptide cleavage product that is formed by proteolytic cleavage of a precursor protein or a mature protein is a claim limitation that must be accorded weight, and which distinguishes claims 1, 7, 10 and 11 from Frazer.

The Examiner's failure to give weight to the above-identified limitation has no factual or legal basis. The Examiner is incorrect to characterize the limitation as "merely a product by process." The term "product-by-process" is properly used with reference to a claim, not a claim limitation. Moreover, the concept of "product-by-process refers" to defining a product by how it is made. The present claims are traditional product claims; they define the claimed chimeric peptides by sole reference to the claimed products, without reference to how they are made. Thus, the limitation that "N" and "C" are amino acids found respectively at the N-terminus or C-terminus of an internal peptide cleavage product that is formed by proteolytic cleavage of a precursor protein or a mature protein does not define how the peptide is made but, rather, defines where the amino acids are situated in protein (e.g., at the N- or C-terminus of an amyloid β protein that is proteolytically derived from APP precursor protein). This feature distinguishes the peptides N and C from other peptides that are not found at either the amino or carboxy termini of a naturally occurring internal cleavage product.

Additionally, upon reading the specification, it is clear that the claims are not limited to chimeric peptides formed by a particular process. The specification sets forth at least two approaches for synthesizing the claimed chimeric peptides. "The chimeric peptides of the present invention can be made by synthetic chemical methods which are well known to the ordinarily skilled artisan." Specification at page 27, lines 11-13. "Alternatively, the longer linear chimeric peptides can be synthesized by well-known recombinant DNA techniques." Specification at page 27, lines 25-26. The fact that alternative processes may be used to make the claimed chimeric peptides demonstrates that claims are standard product claims that define a claimed chimeric peptide by "what it is" rather that "how it is made."

The Examiner, moreover, need look no further than the instant specification for an illustration that the limitation that peptides N and C are 2-5 amino acids found at the N-terminus or C-terminus of an internal peptide cleavage product that is formed by proteolytic cleavage of a precursor protein or a mature protein is a limitation that differentiates the claimed chimeric peptides from other peptides. As set forth in the specification, amyloid β peptide is derived from proteolytic cleavage of amyloid precursor protein (APP). Specification at page 2, lines 4-8. "Naturally-occurring internal cleavage" of APP yields specific, amyloid β isoforms, for example, Aβ1-40, Aβ1-42, Aβ1-43, Aβ3-42, Aβ11-42 and Aβ17-42 Specification at page 19, lines 23-25. Thus, with reference to these isoforms of Aβ, claim 1, for example, is directed to chimeric peptides of formula (I) or (II) where N is selected from among the twelve peptides that are 2-5 amino acids in length and start with the amino acids found respectively at positions 1, 11 and 17of Aβ and C is selected from among the twelve peptides that are 2-5 peptides in length and terminate with the amino acids at positions 40, 42 or 43 of Aβ. Thus, with reference to the aforementioned isoforms, claim 1 calls for to a relatively small number of the possibilities of all of the possible peptides derived from Aβ that are 2-5 amino acids in length. When properly construed, N and C are proper limitations that distinguish the claimed chimeric peptides from all other chimeric peptides. Products of nature can be claimed by reference to their source, assuming the claimed product derived from the source is distinguishable from the product found in nature. *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1329 (Fed. Cir. 2003). Here, the limitation that limitation the claimed chimeric peptides include 2-5 amino acids from the free N- or free C-terminus of a naturally-occurring internal peptide cleavage product that is formed by proteolytic cleavage of a precursor protein or a mature protein is a permissible source limitation.

In the absence of the improper "product by process" analysis, the Examiner provides no factual basis for asserting that the feature that N and C are peptides from the N-terminus or C-terminus of an internal peptide cleavage product that is formed by proteolytic cleavage of a precursor protein or a mature protein "does not place any patentable structure characteristic on the final product, i.e., the claimed chimeric peptide, which would differentiate the claimed peptides made by another process." Frazer fails to disclose a chimeric peptide comprising 2-5 amino acids from the free N- or free C-terminus of a naturally-occurring internal peptide cleavage product that is

formed by proteolytic cleavage of a precursor protein or a mature protein. Frazer thus fails to anticipate the instant claims.

For at least the reasons set out above, Frazer does disclose each limitation of claims 1, 7, 10 and 11. Frazer thus does not anticipate claims 1, 7, 10 and 11. Reconsideration of the claims and withdrawal of the rejection based on Frazer is requested.

III. Conclusion

This application is believed to be in condition for allowance, which is earnestly solicited.

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Respectfully submitted,

By /Mitchell Bernstein/

Mitchell Bernstein
Registration No.: 46,550
DARBY & DARBY P.C.
P.O. Box 770
Church Street Station
New York, New York 10008-0770
(212) 527-7700
(212) 527-7701 (Fax)
Attorneys/Agents For Applicant